Validation of dried blood sampling for infliximab in IBD-patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON43041

Source
ToetsingOnline

Brief title
Dried blood sampling infliximab

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dried Blood Spot, IBD, Infliximab

Outcome measures

Primary outcome

Primary: to investigate feasibility of DBS from finger prick for measuring infliximab drug levels and ATIs compared with the results of venepuncture serum sample measurements.

Secondary outcome

To compare levels of albumin and CRP from DBS with the results of venepuncture serum sample measurement and to investigate feasibility of DBS from finger prick at home.

Study description

Background summary

Higher infliximab (IFX) serum concentrations are associated with increased rates of clinical response, endoscopic healing and lower rates of surgery. The use of anti-TNF therapy is however complicated by loss of response (LOR). The exact mechanism behind LOR is unknown, but it is likely that an increased clearance of anti-TNF plays a role. One of the factors influencing clearance is the formation of antidrug-antibodies, in this case antibodies-to-infliximab (ATIs).
In recent years it has become clear that therapeutic drug monitoring (TDM) can be an important tool to optimize outcome of anti-TNF treatment. The dried blood spot (DBS) sampling method with blood obtained via a finger prick greatly facilitates TDM, since patients can administer this finger prick themselves at any time.
Therapeutic monoclonal antibodies and antidrug-antibodies can be accurately quantified in DBS and anti-TNF measurements in DBS have been previously described in patients with inflammatory bowel disease treated with infliximab or adalimumab (n=20).

Study objective

The aim is to investigate the feasibility of DBS from finger prick for measuring infliximab drug levels and ATIs compared with the results of venepuncture serum sample measurements.
As a secondary objective, measurements of albumin and CRP will also be compared between both methods. Also, feasibility of DBS from finger prick at home will be investigated.

Study design

A longitudinal study of 40 patients with Inflammatory Bowel Disease (IBD) receiving infliximab induction or maintenance treatment. Blood via venepuncture and DBS via finger prick will be obtained simultaneously from each patient at 3 timepoints by a trained employee. One extra DBS will be obtained by the patient himself at home to test the feasibility of DBS at home.

Study burden and risks

Due to participation in this study, 1 extra visit to the outpatient clinic will be needed. Blood will be withdrawn during regular visits for infliximab infusion. During the extra visit a regular venepuncture will be used and a finger prick will be performed for DBS at the same visit by a trained employee. One additional DBS will be obtained by the patient himself at home.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age from 18 years, either male or female
- Diagnosis of IBD
- Receiving infliximab therapy

Exclusion criteria

- Contra-indication to infliximab (TBC, severe infections or congestive heart failure)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58097.018.16

Study results

Date completed:	24-10-2018
Actual enrolment:	40